REMARKS

Upon Amendment, Claims 106-110, 112-118 and 120-121 are pending. Claims 101-105, 111 and 119 have been canceled without prejudice. Claim 106 has been amended to recite that the vesicles consist essentially of one or more phosphatidyl cholines; a salt of one or more non-steroidal anti-inflammatory drugs; and one or more of phenol, cresol or benzyl alcohol. Support for this amendment can be found, for example, at page 19, lines 1-4. Claim 106 has been further amended to recite that the composition is administered to the "skin or a mucous membrane of a human or an animal". Similarly, Claims 107-109 have been amended to correct the preamble to recite the method of Claim 106. Finally, Claim 120 has been amended to recite that the vesicular composition is administered. Support for these amendments can be found throughout the specification as originally filed. For example, at Page 1, lines 1-6 and Page 26, lines 24-28. No new matter has been added.

Reconsideration and withdrawal of the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is believed to be in condition for allowance.

The right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications is respectfully reserved.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 106-110 and 112-131 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject mater regarded as the invention. In particular, the Office Action states that the term "one or more stabilizers" is allegedly unclear. Without conceding the validity of this assertion, and solely for the purposes of advancing prosecution, the term "one or more stabilizers" has been amended to recite "one or more of phenol, cresol or benzyl alcohol."

Similarly, the Office Action states that the transport trough mucous membranes is allegedly unclear in light of the claimed administration to the skin. Without conceding the validity of this assertion, and solely for the purposes of advancing prosecution, Claim 106 has been amended to recite that the composition is administered "to the skin or a mucous membrane of a human or an animal".

Support for these amendments can be found throughout the specification as originally filed. For example, at Page 1, lines 1-6, and at page 19, lines 1-4. No new matter has been added.

As such, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, is respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 106-110, 114-118 and 121 stand rejected under 35 USC §102(b) as being allegedly anticipated by United States Patent No. 4,937,254 to Sheffield *et al.* ("Sheffield").

Claims 106-110, 112-113, and 116-118 stand rejected under 35 USC §102(b) as being allegedly anticipated by United States Patent No. 5,585,109 to Hayward *et al.* ("Hayward").

Sheffield does not disclose a vesicle consisting essentially of one or more phosphatidyl cholines; a salt of one or more NSAIDS and one or more phenol, cresol or benzyl alcohol.

Similarly, Hayward does not disclose a vesicle consisting essentially of one or more phosphatidyl cholines; a salt of one or more NSAIDS and one or more phenol, cresol or benzyl alcohol.

As such, neither Sheffield nor Hayward discloses all of the claimed elements. Therefore, it is believed that the rejections should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 106-110 and 112-121 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Hayward or Sheffield in view of United States Patent No. 5,209,720 to Unger ("Unger").

As previously discussed, neither Sheffield nor Hayward teaches or discloses a vesicle comprising phenol, cresol or benzyl alcohol, much less a vesicle consisting essentially of one or more phosphatidyl cholines; a salt of one or more NSAIDS; and one or more of phenol, cresol or benzyl alcohol.

Unger does not remedy the deficiencies of Sheffield or Hayward. The Office Action alleges that Unger teaches the addition of a bacteriostatic agent such as benzyl alcohol to prevent bacterial degradation on storage and the addition of an antioxidant such as tocopherol or ascorbic acid to prevent oxidation of the lipids. It is believed and respectfully asserted that the Office Action's characterization of Unger is incorrect. Unger states "***for storage prior to use***, the liposomes of the present invention may be suspended in an aqueous solution, such as a saline solution... or simply water, and stored.... Preferably, the water is sterile.... Bacteriostatic agents may also be included with the liposomes ***to prevent bacterial degradation on storage***." (Column 6, line 52 to Column 7, line 13). Even though Unger describes the inclusion of bacteriostatic agents and antioxidants ***in the storage medium*** for the liposomes, Unger does not suggest, much less describe the inclusion of the bacteriostatic agents or antioxidants in the liposomes themselves. Indeed, the liposome vesicles of Unger do not include any bacteriostatic agent or antioxidant. Therefore, any combination of Hayward or Sheffield with Unger cannot and does not provide the vesicles of the presently claimed methods.

Unger does not teach the inclusion of phenol, cresol or benzyl alcohol in liposomes. As such, Unger cannot and does not provide a reasonable expectation that the presently claimed methods,

which comprise administering a vesicle consisting essentially of one or more phosphatidyl cholines; a salt of one or more NSAIDS and one or more phenol, cresol or benzyl alcohol, would have been successful.

The Office has failed to provide a reference that teaches the inclusion of phenol, cresol or benzyl alcohol in a vesicle such as the ones of the claimed methods. Indeed, one of ordinary skill in the art would have lacked an apparent reason to combine the shelf-life extending agents described in Unger for storage of a liposomal formulation directly into the vesicles of the liposomal formulations described by Sheffield and/or Hayward.

Additionally, with respect to Hayward, the salicylic acid compositions of Hayward are composed of only free salicylic acids. Indeed, Hayward specifically teaches away from the use of the salt of salicylic acid. Specifically, Hayward states hat "the formation of salts of salicylic acid, such as sodium salicylate formed by the combination of salicylic acid and sodium hydroxide, greatly improves the water solubility of the free acid, but ***substantially modifies the biological response*** to salicylic acid." Indeed, Hayward clearly discourages the use of sodium salicylate. In particular, Hayward seeks to ensure "that the greater proportion of the salicylic acid in the formulation remains as the free acid" (Column 2, lines 42-49) and to "sustain a neutral pH... without neutralizing the salicylic acid to the corresponding salicylate" (Column 4, lines 27-31). Indeed, in each of the specified examples, salicylic acid is used for encapsulation in its acid form and is never used as a salt. Based on this teaching, one of skill in the art would have lacked an apparent reason to incorporate the salt form of salicylic acid, let alone any other NSAID salt, into the vesicles of Hayward without substantially modifying the biological response of the NSAID.

Accordingly, reconsideration and withdrawal of all rejections under 35 U.S.C. § 103 of claims 106-110, and 112-121 is respectfully requested.

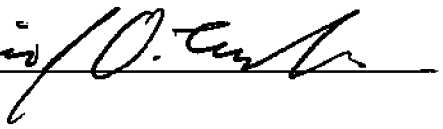
CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 35946.701.831).

Respectfully submitted,

Dated: October 30, 2007

By 

Nicholas J. DiCeglie, Jr.
Registration No. 51,615
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
(650)493-9300
Customer No. 021971